

Ms. Judith Jussim

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857-0003

RE: Docket No. 98N-1265

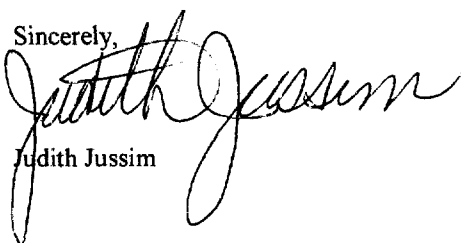
Dear FDA:

I am writing to urge that MOU Section 503A, on pharmacy compounding, be amended. The MOU, as proposed, would keep me, and thousands of others like me who have atypical reactions to noncompounded drugs, from getting the medical care that they need. We often cannot tolerate ingredients in specific patented medicines and need compounded alternatives, often with natural ingredients. Since these may only be obtainable by mail order, the MOU, by restricting access to drugs not compounded in a person's state of residence, is blocking our access to sometimes critical medical care. In addition, by restricting the markets of pharmacies that specialize in compounding, the MOU may force these specialty pharmacies out of business. I have no economic interest in these pharmacies; I simply depend on them for prescription medications. I do not want them driven to bankruptcy.

By restricting access to these medications for people who are often disabled or chronically ill, the FDA is violating the intent Congress has expressed in related legislation, such as the Americans with Disabilities Act, that are clearly intended to improve life for people with disabilities and chronic health problems.

It is vital that the MOU be amended to eliminate the restrictions on compounding and distributing compounded drugs across state lines.

Sincerely,



Judith Jussim

98N-1265

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